REMARKS

Claims 19 and 21 - 35 are currently pending.

In the Office Action, claims 19 and 21 – 35 were rejected under 35 USC §112, as allegedly being non-enabled for the entire scope of prion diseases and salts of guanidine. The assertions made in this rejection are respectfully traversed.

First, the rejection states that the specification only enables the salt guanidine HCl, and that it is unpredictable whether other salts would work because they may be of different sizes, polarity and electronegativity. It is asserted that structural changes could result in a drastic change in activity of the compound. However, it is respectfully submitted that in the pharmaceutical arts, drugs are typically administered in various salt forms; it is not the salt itself that exerts the effect of the drug, because in body fluids the salt becomes dissociated, it is the free base of the drug. That is, in the present situation, it is the guanidine that is active at the receptor site, not the entire salt form. Thus, any available salt of guanidine can be used, and would only depend on such factors typically taken into consideration in the pharmaceutical industry, such as solubility, ease of use, stability, and availability. Guanidine HCl is a preferred embodiment of the present invention, especially given its established use in pharmaceuticals. The rejection, however, fails to establish a reasonable basis for requiring the claims to be limited to such a salt, or any small subgenus of guanidine salts of similar polarity, size and electronegativity.

Second, the rejection does not provide a basis for limiting the claims to only certain, named prion diseases. The rejection merely states, "...based on Applicant's specification, Applicant is not entitled to all prion diseases." The specification states at page 10, lines 16 – 18, that prion diseases are disorders associated or caused by the conversion of the cellular type of prion protein to the scrapie type of prion protein or its consequent aggregation. While the specification (and claim 23) mentions a number of the most important encephalopathies, it was not intended to be an exhaustive list. The burden is on the Patent Office to establish a reasonable basis for inferring that the treatment would not work on a prion disease other than those in claim 23, and without that the presumption of patentability lies in Applicants' favor.

For the reasons stated above, the invention as claimed is fully enabled by the specification. Withdrawal of this rejection is therefore deemed proper.

Claims 19 and 22 – 29 were rejected under 35 USC §102(e) over Kaddurah-Daouk et al. This rejection is respectfully traversed.

The rejection refers to guanidinoacetate as a "guanidine salt". This is not correct, however. That is, the reference does not teach "guanidine acetate", which may be recognized as a salt of guanidine, but discloses a molecule whose structure contains an acetate moiety chemically bonded to a guanidine moiety. The guanidinoacetate molecule is a base that would likely form a salt, such as sodium guanidinoacetate, but it is not itself a salt form. See, for example, Kaddurah-Daouk' s previous US Patent No. 5,324,731, at Table 4, which shows

the structure of various guanidinoacetates. These are not the same as "guanidine salts".

Thus, the cited publication does not teach the presently claimed invention in the least. Reconsideration and withdrawal are earnestly requested.

Similarly, the rejection of claim 30 under 103(a) should be withdrawn, because the molecule disclosed in the Kaddurah-Daouk reference is not at all related to guanidine salts.

Applicants respectfully submit that claims 19 and 21 – 35 are in condition for allowance. Prompt issuance of a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned at the number or email listed below should he believe there are any remaining issues that could be more easily resolved by direct communication.

Respectfully submitted,

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